(HF–32), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD, 20857, 301–827–3340.

SUPPLEMENTARY INFORMATION: FDA is announcing the formation of a subcommittee of the Science Board. The subcommittee has been established to address issues related to the scientific quality, mission relevance, and scientific management and leadership of research programs conducted by FDA. The subcommittee will meet several times over the next 2 years to collect and review information on FDA's scientific research programs and to discuss a validated process for a coordinated, external, scientific peer review of the agency's research programs. The subcommittee's findings will be presented to the Science Board for full public discussion at future meetings that will be announced in the **Federal Register** prior to the meetings. This notice is issued under the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92–463 (5 U.S.C. app.2)).

Dated: December 4, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–32276 Filed 12–9–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97F–0504]

The Goodyear Tire and Rubber Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the Goodyear Tire and Rubber Co. has filed a petition proposing that the food additive regulations be amended to provide for the expanded safe use of butylated reaction product of *p*-cresol and dicyclopentadiene for use as an antioxidant in acrylonitrile/butadiene/styrene copolymers in contact with food.

FOR FURTHER INFORMATION CONTACT: Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFS–205), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3086.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 8B4561) has been filed by The Goodyear Tire and Rubber Co., c/o Keller and Heckman LLP, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposes to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to provide for the expanded safe use of butylated reaction product of *p*-cresol and dicyclopentadiene for use as an antioxidant in acrylonitrile/butadiene/styrene copolymers in contact with food.

The agency has determined under 21 CFR 25.32(i) that this action is of the type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: December 2, 1997.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 97–32358 Filed 12–9–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M–0501]

Abbott Laboratories; Premarket Approval of IMx® PSA and AxSYM® PSA Assays

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the supplemental application by Abbott Laboratories, Diagnostics Div., Abbott Park, IL, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the IMx® PSA and AxSYM® PSA assay. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of August 7, 1997, of the approval of the supplemental application.

DATES: Petitions for administrative review by January 9, 1998.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Peter E. Maxim, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1293.

SUPPLEMENTARY INFORMATION: On November 2, 1994, Abbott Laboratories, Diagnostics Div., Abbott Park, IL 60064, submitted to CDRH a supplemental application for premarket approval of IMx® PSA and AxSYM® PSA assays. The devices are microparticle enzyme immunoassays (MEIA) for the quantitative measurement of Prostate Specific Antigen (PSA) in human serum as an aid in the detection of prostate cancer when used in conjunction with digital rectal exam (DRE) in men aged 50 years or older. Prostatic biopsy is required for diagnosis of cancer.

In accordance with the provisions of section 515(c)(2) of the act (21 U.S.C. 360e(c)(2)) as amended by the Safe Medical Devices Act of 1990, this premarket approval application (PMA) was not referred to the Immunology Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

On August 7, 1997, CDRH approved the supplemental application by a letter to the applicant from the Deputy Director of Clinical and Review Policy, Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of